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EXAMINER

TAYLOR, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/515,513

Applicant(s)

LI ET AL.

Examiner

Janell Taylor Cleveland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-63 and 105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-63 is/are allowed.
- 6) ☒ Claim(s) 33-46 and 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The request filed on July 16, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/515,513 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 33-39 and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Sloma.

Claim 33 is drawn to a method for synthesizing one or more cDNA molecules or population of cDNA molecules comprising: mixing at least one mRNA template, poly A RNA template or population of such templates with at least one polypeptide having reverse transcriptase activity; under conditions that inhibit, prevent, reduce, or substantially reduce internal priming. Claim 34 is drawn to the polypeptide being a reverse transcriptase which is selected from the group consisting of M-MLV RT, RSV RT, AMV RT, MAV RT, and HIV RT, and derivatives and fragments thereof. Claim 35 is drawn to the reverse transcriptase having reduced RNase H activity. Claim 36 is drawn to the primers hybridizing at temperatures that inhibit, prevent, reduce, or substantially reduce internal priming. Claim 37 states that those temperatures are between 10 and 90 degrees C. Claim 38 states that those temperatures are between 20 and 75 degrees C.

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Claim 39 states that those temperatures are between 45 and 65 degrees C. Claim 105 is drawn to the method of claim 33, wherein said one or more DNA molecules are one or more cDNA molecules.

Sloma teaches "Synthesis of cDNA employs avian myeloblastosis virus reverse transcriptase. This enzyme catalyzes the synthesis of a single strand of DNA from deoxynucleoside triphosphates on the mRNA template. The poly r(A) tail of mRNA permits oligo (dT) ...to be used as a primer for cDNA synthesis...cDNA synthesis is generally conducted by combining the mRNA, the dNTPs, the oligo (dT) and the reverse transcriptase in a properly buffered solution....This solution is incubated at an elevated temperature of about 40-50 degrees C, for a time sufficient to allow formation of the cDNA copy...(Col. 4, lines 16-37). Therefore, Sloma teaches synthesis of a cDNA molecule, in the presence of an RT such as AMV, which is known to not possess RNase H properties, at an elevated temperature.

Sloma therefore teach all of the limitations of claims 33-39.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloma as applied to claims 33-39 above, and further in view of Copeland et al.

Claims 40-42 depend from claim 33, but recite the further limitation that the amount of primer to template ratio is between 15:1 and 1:15, between 10:1 and 1:10, and between 5:1 and 1:5, respectively.

Sloma does not teach primer: template ratios.

Copeland et al. teach that the primer: template ratio is in a ratio of 1:1 in regards to the synthesis of DNA. (Col. 21-22, lines 65-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sloma with that of Copeland. This is because it was well known in the art at the time of the invention that a variety of template: primer ratios were useable in different circumstances, depending upon the needs of that given reaction. It was also well known that lowering the primer: template ratio would have caused synthesis to proceed at a slower rate, which would have been beneficial in many applications such as cDNA synthesis. It would not have been an undue experimentation on the part of the practitioner to vary the primer: template ratio until the maximum amount of cDNA product, at the longest length possible, was obtained.

5. Claims 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloma as applied to claims 33-39 above, and further in view of Ranu.

The claims are drawn to the method of claim 33, with the further limitation that a primer is used which has high specificity, and is from a length of 20-100 bases, 20-75 bases, 20-50 bases, and 25-35 bases, respectively.

Sloma does not teach the length of the primers used.

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Ranu teaches the use of a 50-mer primer as the antisense oligonucleotide in the synthesis of cDNA from mRNA. (Col. 15, lines 40-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the primer of Sloma with that of the 50-mer of Ranu, or of any other reasonable size for that matter. This is because it was well known in the art at the time of the invention that primers of many different lengths were readily useable to prime the synthesis of mRNA. Furthermore, it was also well known that the longer the primer, the higher the specificity of the priming. Therefore, one of ordinary skill in the art would have been motivated to use a long primer in the synthesis of cDNA. This is because it would have conferred a higher degree of accuracy in the product, allowing for a longer length product if that primer were directed toward the poly A tail.

Summary

Claims 33-46 and 105 are rejected. Claims 47-63 are free of the prior art and are considered allowable. These claims are free of the prior art because they teach an inhibitor of the polypeptide having reverse transcriptase activity during the synthesis of a cDNA molecule from an mRNA template.

Response to Arguments

6. Applicant's arguments filed 7/16/2001 have been fully considered but they are not persuasive in regards to the 102(b) and 103(a) rejections over claims 33-46 and 105. In regards to the arguments over the rejection of claims 33-39 and 105, Applicant asserts that the rejection is improper because "Sloma does not teach or suggest the use of elevated temperature to decrease internal priming during the annealing phase of the

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reaction; rather Sloma teaches the use of elevated temperatures during the DNA synthesis reaction." However, the claims do not specify at what point the temperature is elevated and even those claims, such as claim 36, which state that conditions comprise annealing or hybridizing one or more primers to said template at temperatures that inhibit internal primers are considered anticipated by Sloma. This is because Sloma teaches the elevated temperatures are present during the formation of the cDNA copy (Col. 4, lines 35-37). The formation of the cDNA copy is taken as including the hybridization of primers to the mRNA, which is a necessary step in the formation of cDNA. Furthermore, Applicant points to the teachings of Sloma in column 12 that state that the mixture is kept on ice until it is incubated. However, it is well known in the art that solutions are often kept on ice before annealing or hybridization takes place, and that a certain temperature level must be present in order for this event to occur, which is above the freezing level. Furthermore, it is well known that annealing and hybridization takes place within the temperature range specified by Sloma et al., approximately 46 degrees. In regards to the 103(a) rejection of Sloma in view of Copeland and Sloma in view of Ranu, pertaining to claims 40-46, Applicant states that the same arguments applicable to the 102 rejection apply to the 103 rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

September 12, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

9/17/01